

REMARKS

Claims 1, 16-19, 24, 26, 32, 33, 35, and 40-43 have been amended herein. Claims 16-18 have been withdrawn from consideration. Claims 8-15, 20-23, and 25 were cancelled in a previous Response(s). New claims 44-50 have been added. Claims 1-7, 19, 24, and 26-50 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendment to the Specification

No new matter has been added by the amendment to the specification made herein. Paragraph [0011] has been amended only to correct a typographical error.

Amendments to the Claims

No new matter has been added by the amendments to claims 1 and 40 made herein. These claims were amended to clarify that there are two sections of tissue. The sections of tissue are brought into close apposition utilizing the described apparatus. This amendment is supported by the specification as originally filed, for example, in paragraph [0039] of the published application.

No new matter has been added by the amendments to claims 1, 26, and 40 made herein. These claims were amended to clarify that the implement or implant is passed through tissue by magnetic force alone. This amendment is supported throughout the specification as originally filed, for example, in the abstract and paragraphs [0041]; [0043]; [0050]; and [0063] of the published application. It is noted that the parent application, now an issued U.S. patent (serial number 10/005,652, filed on December 3, 2001, now U.S. Patent 6,719,765), includes claims drawn to methods of passing implements through tissue by magnetic force alone.

No new matter has been added by the amendments to claims 1, 16-19, 24, and 40-43 made herein. These claims were amended to provide proper antecedent basis in language.

No new matter has been added by the amendments to claims 26, 32, 33, 35, and 40-43 made herein. These claims were amended to correct inadvertent grammatical and typographical errors.

No new matter has been added by the addition of new claims 44-46. These claims were added to clarify that the location of the magnetic field can be altered to provide directional control of the implement or implant as it is driven through the tissue. This subject matter is supported in the specification as originally filed, for example, in paragraph [0008] of the published application.

No new matter has been added by the addition of new claims 47-50. These claims were added to clarify that both the magnetic field generator and the magnetizable material are electromagnets that are selectively activatable and deactivatable to move the medical implement back and forth through the tissue. This subject matter is supported in the specification as originally filed, for example, in paragraphs [0014] and [0044] and Figure 3 of the published application.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1 and 40-43 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner states that there is insufficient antecedent basis for the following claim limitations: “said first tissue” in line 6 of claim 1 and in line 9 of claim 40 and “said handle” in line 4 of each of claims 41-43.

Claims 1 and 40-43 have been amended herein for proper antecedent basis for all the limitations recited in the claim language. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 40-43 under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 2, 19, 24, 26-29, 31, 35, 37, 40, and 41 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Holmes (U.S. Patent 5,417,701; hereinafter “Holmes ‘701”). For reasons set forth below, Applicant respectfully submit that this rejection should be withdrawn.

Holmes ‘701

Holmes ‘701 discloses an instrument for use in endoscopic surgery. *See* abstract and column 1, lines 6-8. This instrument is a magnetic needle holder utilized for prevention of dropped needles during surgical procedures and uses a magnet to properly position, orient, and hold a needle within its jaws. The magnet is embedded in one of the jaws and when the jaws are near the needle, the magnet attracts the needle to it, causing the needle to move to a predetermined position on the jaw containing the magnet. *See* column 1, line 65 to column 2, line 3. The instrument **10**, shown in Figure 1, includes an elongated barrel **12**, a pair of jaws **18** and **20** at one end **14**, and at the opposite end a scissor-like control mechanism **16**. The jaws grasp and release a needle. The upper jaw **18** is movable and the lower jaw **20** is stationary relative to the elongated barrel **12**. Jaw **18** rotates about pivot **22**, to open and close the jaws. The control mechanism **16** controls the pivot movement of jaw **18**, via a rod **24**, which runs between them through the interior of barrel **12**. *See* column 3, lines 6-14 and Figure 1. The instrument also includes a wire **40**, which is attached to and moves in parallel with jaw **18** and operates to push the needle out of the groove **34** as the jaws are opened to release the needle. *See* column 3, lines 40-42 and Figure 2.

Holmes ‘701 additionally discloses a suturing procedure that may be performed with one or two instruments. For example, if a surgeon uses a single instrument, he/she grasps a needle with the instrument, positions the needle in the jaws and guides the needle through the tissue,

releases the needle, and re-grasps the exposed end of the needle. He/she then re-positions the needle and again inserts the needle into the tissue in the same manner. *See* column 2, lines 30-33 and column 4, lines 18-21 and lines 60-68. When using two instruments, the surgeon proceeds in the same manner as when using a single instrument, except that a second instrument is used to grasp the needle and pull it through the tissue. The second instrument may include a magnet, preferably of lesser strength than the magnet in the first instrument. When the second instrument pulls the needle out of the tissue, the included magnet draws the needle into the proper position in the jaws of the instrument and holds the needle in this position until the needle is transferred back to first instrument to continue the suturing procedure. In order to transfer the needle, the surgeon brings the two instruments together and opens both sets of jaws, and because of the greater strength of the magnet in the first instrument, the needle moves from its position in the second set of jaws to its previous position in the first set of jaws. *See* column 2, lines 8-29 and column 4, lines 12-59.

Instant Invention

The instant invention, as currently claimed, relates *inter alia* to an apparatus or instrument for passing a medical implement or implant through tissue using magnetic, rather than mechanical force. *See*, for example, abstract and paragraphs [0007], [0009], [0041], and [0043] of the published application. Generally, the medical implement or implant is provided with a magnetic component, placed on a first side of a tissue, a magnetic field is established on a second side of the tissue, and at least one of magnetic component and magnetic field is manipulated to drive the implement or implant through the tissue. *See*, for example, abstract and paragraph [0007] of the published application.

In one embodiment, the apparatus has two tissue-engaging surfaces; the first holds the medical implement or implant and contacts a first tissue section or side and the second contacts a second tissue section or side and penetrates the medical implement or implant into the tissue. The second tissue-engaging surface is movable relative to the first tissue-engaging surface. The

medical implement or implant can be, for example, a surgical needle or suture anchor. The apparatus also includes magnetizable material and a magnetic field generator, the magnetizable material being disposed within either the first or second tissue-engaging surface and the magnetic field generator being disposed in the tissue-engaging surface not containing the magnetizable material. The magnetizable material can be, for example, a permanent magnet or an electromagnet. When in use, the magnetic field generator generates a magnetic field to move the magnetizable material and drives the medical implement or implant through tissue. *See* paragraphs [0039]-[0047] and Figures 1-3 of the published application.

In a similar embodiment, the apparatus includes two handles connected by a pivot. The first tissue-engaging surface is connected to the first handle and the second tissue-engaging surface is connected to the second handle. *See* paragraphs [0053]-[0057] and Figures 9-11 of the published application.

In another embodiment, a surgical instrument is used to deliver an implant through tissue. The surgical instrument includes a body, a carrier located on the body, a tip at the distal end of the body for insertion through the tissue, and a magnetic element located on the body. The implant can be removably secured to the carrier. The magnetic element interacts with a magnetic field external to the tissue and drives the implant into the tissue. *See* paragraph [0009] of the published application.

Regardless of the embodiment or exact nature of the magnetic component, the magnetic field location can be altered to provide directional control of the medical implement or implant as it is driven through tissue. For example, if the magnetic field generator is a permanent magnet the magnetic field can be varied by changing the location and orientation of the permanent magnet. If the magnetic field generator is an electromagnet, the magnetic field can be changed by using a controller. Furthermore, interaction between magnetic fields can also be used to move the implement or implant after it has penetrated the tissue. *See* paragraphs [0008], [0014], [0042], [0044], and Figure 3.

Argument

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131.

The apparatus (or implement) for moving a medical implement or implant through tissue, as claimed in the instant invention, is distinct from the instrument with a magnetic needle holder disclosed by Holmes '701.

During operation of the described apparatus, magnetic attraction between magnetizable materials and a magnetic field drives a medical implement or implant through tissue. Movement of the implement results from magnetic force, rather than mechanical force. Thus, in the instant invention, medical implements or implants are moved through tissue substantially free of mechanical assistance. As noted above, this concept is found throughout the specification as originally filed. Furthermore, in the "Background of the Invention" section (paragraphs [0003]-[0006]), a need for surgical instruments that do not rely solely on mechanical force to pass medical implements through tissue is stated. Thus, it was clear from the beginning that an intention of the invention is to provide a surgical apparatus that relies primarily on a force other than a mechanical force to move medical devices through tissue.

In contrast, Holmes '701 discloses a surgical instrument that relies on mechanical force to move medical implements through tissue. This instrument grasps a needle between two jaws for insertion of the needle through the tissue. The needle remains grasped in the jaws when it is inserted into the tissue. A second similar instrument can be used to grasp the needle on the opposite side of the tissue to pull the needle completely through the tissue. A magnet is embedded within one of the jaws to properly position, orient, and hold a needle in place. This magnetic holder is useful to prevent difficulties, such as dropped needles, encountered by surgeons that have to release and re-grasp needles multiple times during a procedure. These

problems are discussed in the “Background of the Invention” section of Holmes ‘701 (column 1). There is no mention of the needle being passed through the tissue by the magnet. Holmes ‘701 does not disclose any purpose for the magnet other than to secure the needle.

Furthermore, in the instant invention, the magnetic field location can be altered to provide directional control of the medical implement or implant as it is driven through tissue or even after it has already been driven through the tissue. In Holmes ‘701, the needle is in a fixed position and can only move directly from side to side. Additionally, considering that the needle is grasped by and fixed between the jaws of the instrument when it is pushed and pulled through the tissue, it would not be possible for the magnet to move the needle as the magnetic force is occupied by holding the needle in place. Thus, it is clear that the mechanical force supplied by the surgeon, and not the magnetic force, is moving the needle through the tissue.

Accordingly, Holmes ‘701 does not disclose an apparatus wherein a medical implement is moved through tissue by magnetic attraction. Therefore, Holmes ‘701 does not teach each and every element of the invention as currently claimed.

Independent claims 1, 26, and 40 are not anticipated by Holmes ‘701 under 35 U.S.C. § 102(b). As claims 2, 19, 24, 35, and 37 depend from claim 1, claims 28, 29 and 31 depend from claim 26, and claim 41 depends from claim 40, these dependent claims necessarily include all of the elements of the base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over the cited patent (Holmes ‘701) for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 2, 19, 24, 26-29, 31, 35, 37, 40, and 41 under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103(a)

Claims 3-7, 30, 32-34, 36, 38, 39, 42, and 43 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Holmes (U.S. Patent 5,417,701; hereinafter “Holmes ‘701” in view of Holmes (U.S. Patent 5,431,670; hereinafter “Holmes ‘670”). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

The teachings of Holmes '701 and the instant invention are applied as above.

Holmes '670

Holmes '670 discloses a surgical instrument similar to that of Holmes '701, *i.e.* both instruments are magnetic needle holders utilized for prevention of dropped needles during surgical procedures. However, the instrument disclosed by Holmes '670 does not include mechanical jaws and instead includes an electromagnet at the end of an elongated barrel to orient and hold a needle. Wires extending from the electromagnet through the barrel connect to a power source which supplies current to the wires. The power source preferably has multiple power settings for supplying different levels of current. *See* abstract and Figure 1. In order to release the needle from the instrument, the power supply is decreased or turned off.

Additionally, the power setting of the power source may be adjusted to reverse the direction of the current supplied to the electromagnet. This changes the polarity of the electromagnet to repel the needle and thus, releases it from the instrument. *See* column 3, lines 54-64 and column 4, lines 40-50.

Argument

Holmes '670 does not remedy the deficiencies of Holmes '701. Although Holmes '670 discloses an instrument having an electromagnet with reversible polarity, the electromagnet is not used to move the instrument or the needle through tissue. Neither Holmes reference teaches the use of magnetic force for anything other than securing and conveniently releasing the needle from the barrel of the instrument. Thus, even if one of ordinary skill in the art combined the teachings of the cited patents, one would not obtain the apparatus of the instant invention because neither of the cited references teaches movement of a device through tissue using magnetic attraction. Furthermore, one would not be motivated to attempt such a combination because, prior to the instant invention, there was no suggestion that mechanical force was

insufficient and/or undesirable for moving a device through tissue. One of skill in the art would have to know or guess that something other than mechanical force would be preferable.

Regardless, the claims rejected herein under 35 U.S.C. § 103(a) are all dependent claims. Independent claims 1, 26, and 40 are submitted to be patentable over Holmes '701. As discussed above, Applicant further submits that the inclusion of Holmes '670 fails to overcome the deficiencies of Holmes' 701. As claims 3-7, 32, 34, 36, 38, and 39 depend from claim 1, claim 30 depends from claim 26, and claims 42 and 43 depend from claim 40, these claims are submitted to be patentable over the cited patents (Holmes '701 and Holmes '670) for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 3-7, 30, 32-34, 36, 38, 39, 42, and 43 under 35 U.S.C. § 103(a).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a three month extension of time pursuant to Section 1.17(a)(3) in the amount of \$525 and the fee for additional claims pursuant to Section 1.16(i) in the amount of \$175 are believed to be due and are being paid via credit card. No additional fees are believed to be due. However, please charge any other required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-002-1).

Respectfully submitted,

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